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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/697,590	10/27/2000	Judith Fitzpatrick	018792/0177	3507

22428 7590 07/28/2003

FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

TURNER, SHARON L

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 07/28/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/697,590

Applicant(s)

FITZPATRICK ET AL.

Examiner

Sharon L. Turner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 3-5, 7-22, 24 and 26-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6, 23 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-53 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>12, 14</u> . | 6) <input type="checkbox"/> Other: |

Response to Amendment

1. The amendment filed 4-14-03 and IDS submissions of 4-14-03 and 5-15-03 have been entered into the record and have been fully considered. Claims 1-53 are pending.
2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.
3. As a result of Applicants amendment, all rejections not reiterated herein have been withdrawn by the Examiner.

Rejections Maintained

Election/Restriction

4. Applicant's election with traverse of Group I, claims 1-10 and 23-25 in part drawn to the extent of the peptide HARL, designated as SEQ ID NO:2, residues 292-295 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the peptides are sufficiently related to at least claims 26-53 directed to various methods of using the peptides and that a thorough search would necessarily encompass a search for the methods of use and would not constitute a serious burden. Applicants argue that the search and examination of overlapping sequences does not represent an undue burden. This is not found persuasive because each of the inventions are patentably distinct as each delineates different sequence structure capable of different effects, functions and use. A search for one would not necessarily constitute a search for the other. Further it is noted that the election of peptide sequence as required in the restriction requirement is as an election of invention and not of species as indicated by

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applicant. A search of any particular sequence does not represent a search of any other and the claim structure does not evidence a proper genus. Rejoinder would only be reconsidered upon the indication of an allowable generic claim with common structure and function as required. The requirement is still deemed proper and is therefore made FINAL.

5. Claims 3-5, 7-22, 24 and 26-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Claim Objections

6. Claims 1-2, 23 and 25 are objected to as reciting an improper Markush Group. M.P.E.P. 803.02 states that:

"Since the decisions in *In re Weber* **, 198 USPQ 328 (CCPA 1978); and *In re Haas*, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention, *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); *Ex Parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility."

Applicants traverse in the response of 4-14-3 on the grounds that Unity of invention exists because the peptides share common utility in the ability to bind neural thread protein, ability to bind immunoglobulin and an ability to bind themselves and

further that the peptides share common structure as they are all derived from the HARLIL sequence.

Applicant's arguments filed 4-14-03 have been fully considered but are not persuasive. Common structure to the elected invention is only shared amongst peptides comprising the HARL sequence. Other peptides lack common structure as defined by this motif. As recited in claims 1-2, 23 and 25 multiple alternative peptides are designated that lack the particular HARL sequence and these structures are uncommon, regardless of similar functional capabilities. Further, with respect to the functional ability to bind, the artisan would expect each of the peptides to exhibit distinct binding affinities, properties or characteristics amongst their various partners based upon divergent structure. For example, the different peptides would be expected to differentially bind to alternative immunoglobulin peptides based upon antigen-antibody specificity in binding.

7. Applicant is advised that should claim 23 be found allowable, claim 25 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The claims are restricted to the extent of the elected invention and thus are deemed duplicates as to that subject matter.

Applicant's argue in the response of 4-14-03 that the claims differ in scope as reciting alternative peptides and language as to different lengths.

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Applicant's arguments filed 4-14-03 have been fully considered but are not persuasive as each claim is written in comprising language and thus are of equal scope as to peptides length "comprising" the HARL sequence and to "homologs" and "mimetics" as recited. Therefore, in contrast to Applicant's distinct wording us, the claims each recite the same scope.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is indefinite as the claim appears to recite a peptide that is at most 29 residues in length, i.e., the peptide comprises at least one and up to 25 additional amino acids flanking either the 3' or 5' end of the sequence HARL. However, the claim also recites "having" which is open language and would allow the peptide to be of greater than 29 residues in length comprising an unlimited number of sequences on both the 3' and 5' ends. Thus, the claim is indefinite as to which interpretation is intended. For the purposes of prior art the broadest reasonable interpretation is adopted which is a peptide of unlimited length, i.e., comprising the sequence HARL.

Applicants argue in the response of 4-14-03 that the claims is definite and is limited in length, thus not reading on the full length molecule.

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Applicant's arguments filed 4-14-03 have been fully considered but are not persuasive. It is noted that Applicants cannot limit the length of the peptide by using comprising language followed by the recitation of between one and 25 additional amino acids. The peptides are still "comprising" and thus may be of unlimited length, reading on the full length peptide.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-2, 6, 23 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Kubota et al., US Patent 5716813 filed 2-26-1996 and issued 2-10-98.

Kubota teach isolated peptide of HARL, see in particular SEQ ID NO:8 of Kubota, residues 11-14. SEQ ID NO:8 is 17 residues in length and thus the peptide meets the claim limitations of claim 6 as recited. Kubota teaches a composition with carrier, see in particular columns 12-13 enzyme trehalose compositions. The peptide is inherently a mimetic as it comprises the relevant residues as presumably claimed in claim 23, SEQ ID NO:2, residues 292-295. Similarly claim 25 is anticipated as residues 91-94 share identity to HARL and based on the recitation that claim 25 (b) is also drawn to residues of SEQ ID NO:2, residues 292-295.

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Applicants argue in the response of 4-14-03 that the Kubota reference is not directed to an isolated peptide but to a stretch of amino acids within a larger protein and upon which a nucleic acid was based.

Applicant's arguments filed 4-14-03 have been fully considered but are not persuasive. Applicants apparently have adopted a preferred definition of peptide different from protein. Yet the Examiner finds no evidence of record in the specification or otherwise would generally serve to limit the residues of a peptide from a protein. Both molecules are composed of stretches of amino acids and thus the terms are interchangeable absent evidence of definition in the specification to the contrary. Never the less in contrast to the Applicants analysis, Kubota teaches as set forth above an isolated peptide of 17 residues in length that harbors the HARL motif. While it is true that the peptide sequence is also noted to be included in the larger enzyme proteins of SEQ ID NO:2 and 4 for example, Kubota notes SEQ ID NO:8's in Examples 1-2, and 2, see in particular columns 14-15 and 16-17 for example with comparison also to SEQ ID NO:11 and d12. Thus, Kubota teaches the 17 residue peptide of SEQ ID NO:8 comprising the HARL motif in addition to larger proteins comprising the HARL sequence. Thus, the reference teachings anticipate the claimed invention.

New Rejections Based on Amendment

12. Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in

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the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 6 has been amended to recite "between one and 25" with respect to the additional amino acids flanking the 5' and 3' ends. The amendment was made without notation of support in the specification as originally filed and thus the recitation constitutes new matter absent evidence for support. It is noted however that the recitation fails to limit the length of the peptides as apparently intended via Applicant's arguments with respect to the 112 second paragraph rejection.

Status of Claims

13. No claims are allowed.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.


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- 15. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
July 24, 2003


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600